K061982

VI. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Jan. 31, 2007

FEB 7 2007

1. Submission Applicant & Correspondent:

Name:	Osteotech, Inc.
Address:	51 James Way Eatontown, NJ 07724
Phone No.:	(732) 542-2800
Contact Person:	Chris Talbot

2. Name of Product:

Trade/Proprietary/Model Name:	PLEXUR P
Common or Usual Name:	Bone Void Filler
Classification Name:	Resorbable Bone Void Filler

3. Devices to Which New Product is Substantially Equivalent:

PLEXUR P is substantially equivalent, for the purpose of this 510(k), to other devices that have received 510(k) clearance for similar indications for use.

4. Device Description:

PLEXUR P is a bone void filler that contains as its principal constituents processed human allograft bone tissue and a resorbable polymer. PLEXUR P is produced in various physical forms/shapes/geometries and may be further shaped or cut by the surgeon to meet the particular needs and preferences of the surgeon. PLEXUR P is intended for use as a bone void filler in bony voids or gaps of the skeletal system (i.e., extremities, pelvis) not intrinsic to the stability of the bony structure. PLEXUR P is provided in ready-to-use form in various package sizes by volume or dimension and is intended for single patient use.

5. Intended Use/Indications

PLEXUR P is intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. PLEXUR P is resorbed/remodeled and is replaced by host bone during the healing process.

6. Technical Comparison

PLEXUR P is substantially equivalent to one or more of the predicate devices with respect to materials. PLEXUR P contains human allograft bone tissue, as does one or more of the predicate devices. PLEXUR P also contains resorbable polymer of the same type as those in one or more of the predicate devices. Also, like one or more of the predicate devices, PLEXUR P is provided ready-to-use in various forms that can be cut or shaped by the user into various shapes or sizes.

7. Performance Data

The results of studies in animals showed that PLEXUR P supports bone in-growth and new bone formation.

8. Viral Inactivation

In the production of Plexur P, the allograft bone is subjected to processing steps that have been shown to inactivate viruses, including HIV, hepatitis B and C and CMV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Osteotech, Incorporated
c/o Mr. Christopher W. Talbot
Director of Regulatory Affairs
51 James Way
Eatontown, New Jersey 07724

FEB 7 2007

Re: K061982
Trade Name: Plexur P
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: November 17, 2006
Received: November 20, 2006

Dear Mr. Talbot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

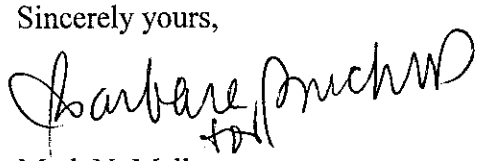
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Indications for Use – Statement

510(k) Number (if known): K061982

Device Name: PLEXUR P

Indications for Use:

PLEXUR P is intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. PLEXUR P is resorbed/remodeled and is replaced by host bone during the healing process.

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Melum

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061982